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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,380	08/23/2000	Floyd H. Chilton		1698

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EXAMINER

JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/644,380

Applicant(s)

CHILTON, FLOYD H.

Examiner

Shaojia A Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on October 6, 2003 in Paper No. 18 wherein claims 52-55 have been amended and claims 1-51 have been cancelled previously.

Currently, Currently, claims 52-55 are pending in this application.

Applicant's amendment and remarks filed on October 6, 2003 in Paper No. 18 with respect to the rejection of claims 52-55 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions, i.e., "about 19.29 weight percent water" and "minor ingredients" in claim 52 of record stated in the Office Action dated July 1, 2003 have been fully considered and found persuasive to remove the rejection since claim 52 has been amended. Therefore, the said rejection is withdrawn.

Claim Objection

Claim 55 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the base claim 52 of record in the previous Office Action July 1, 2003. Applicant's remarks with respect to this objection is not found persuasive.

The independent claim 52 is directed to a composition "consisting essentially of" recited ingredients and "minor ingredients selected from ...". However, the transitional phrase "comprising" is employed in the dependent claim 55. Applicant is requested to note that the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See MPEP 2111.03. As also

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noted in MPEP 2111.03 that a claim which depends from a claim which “consists essentially of” the recited elements or steps cannot add an element or step, because the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis added). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). See MPEP 2111.03.

In the instant case, the dependent claim 55 employing the transitional phrase “comprising” is broader than the scope of the base claim and therefore improper. Applicant is suggested or required to amend claim 55 by changing the transitional phrase “comprising”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 52-55 as amended now are rejected under 35 U.S.C. 103(a) as being unpatentable over DeMichele et al. (5,223,285) in view of Igarashi et al. (EP 782827) and Kahn et al. (4,154,863) for the same reasons of record in the previous Office Action July 1, 2003.

DeMichele et al. discloses that fish oils (marine oils) are well known to contain eicosapentaenic acid (EPA) and borage oil is also well known to contain γ -linolenic acid (GLA). Fish oils (marine oils) in 20% by weight and borage oil in 20% by weight are known to be used in a nutritional composition or a liquid nutritional product (see the particular formulation of Blend C at Table 2 at col.9 lines 32-65) according to DeMichele et al. Thus the sum of oils (marine oils and borage oil) is 40% by weight which would read on the instantly claimed about 35% of oils in claim 52. The preferred nutritional compositions of DeMichele et al. comprise fish oil and borage oil, and water, sucrose, and stabilizer, and favoring agents (see col.15 line 65 to col.16 line 61, especially Table 7; Table 8 at col.17).

DeMichele et al. does not expressly disclose the employment of glycerin and particular minor ingredients in the particular composition herein. DeMichele et al. does not expressly disclose the particular amounts of the ingredients in the particular composition herein.

Igarashi et al. teaches that glycerin is a well known food-additive and used in food or nutritional composition such as the composition therein comprising omega-3 and omega-6 unsaturated fatty acids (see page 15 line 37 and page 10).

Kahn et al. teaches that the instant minor ingredients such as xanthan gum (a known stabilizer for food composition), colorant, sorbic acid, and palmitate, are known to be used in a nutritional composition or food composition (see col.9 lines 21, 40, and 50, col.10 lines 15, 25-26, and 41-44, and particular compositions at col. 13 lines 50-67, col.15 lines 30-46, col.16 lines 20-34, col.17 lines 15-30, col.18 lines 11-24).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ glycerin and particular minor ingredients in a nutritional composition, and to optimize the amounts of the ingredients in a nutritional composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ glycerin and particular minor ingredients in a nutritional composition herein since glycerin is known to be useful in a nutritional composition comprising fatty acids according to Igarashi et al.

Additionally, one having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant minor ingredients such as xanthan gum, colorant, sorbic acid, and palmitate in a nutrition composition since these ingredients are well known to be used in a nutritional composition or food composition according to Kahn et al.

Further, one of ordinary skill in the art would have been motivated to optimize the effective amounts of active ingredients in a nutritional composition or a food composition because the optimization of known effective amounts of known ingredients to be administered is considered well within conventional skills in food and nutritional science or industry, involving merely routine skill in the art. It has been held that it is within the

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skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Applicant's remarks filed on October 6, 2003 in Paper No. 18 with respect to this rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Additionally, Applicant's argument in regard to that DeMichele et al. (5,223,285) does not teach or disclose the intended use herein, rather solving the problem of malnutrition due to reduced nutrient intake, is not found persuasive. Applicant is requested to note that it is well settled that "intended use" of a composition or product, i.e., "for diminishing symptoms of inflammatory disorders", will not further limit claims drawn to a composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Applicant's arguments regarding that this rejection is merely improper hindsight reconstruction of the Applicant's claimed invention have been considered but are not found persuasive. It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

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applicant's disclosure, such a reconstruction is proper. In re McLaughlin , 170 USPQ 209 (CCPA 1971). See MPEP 2145.

In the instant case, as discussed above, Fish oils (marine oils) in 20% by weight and borage oil in 20% by weight are known to be used in a nutritional composition or a liquid nutritional product (see the particular formulation of Blend C at Table 2 at col.9 lines 32-65) according to DeMichele et al. Thus the sum of oils (marine oils and borage oil) is 40% by weight which would read on the instantly claimed about 35% of oils in claim 52.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
December 30, 2003


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

1/12/04